REMARKS

In the outstanding Office action, claims 22-49 were presented for examination. Claims 24, 26, 41 and 43 were withdrawn from consideration. Claims 23, 25, 27-40, 42 and 44-49 were rejected. Claims 23, 27, 28-33, 38-40, 44-47 and 49 were objected to. In this amendment applicant has amended claims 31-33 and 39 and cancelled the withdrawn claims, *without prejudice*. Accordingly, after entry of this amendment, claims 22, 23, 25, 27-40 and 44-49 will be pending. As will be discussed in detail below, it is believed that the application is in condition for allowance.

Specification

The specification has been amended on the first page to reference the parent application.

Claim Amendments

Claim 31 has been amended to overcome the rejection by making explicit language that was inherent in the claim prior to amendment.

Claim 32 has been amended, without narrowing, to overcome the rejection.

Claim 33 has been amended to more explicitly define the polar and apolar parts of the recited collagen-like peptide. Support for this amendment can be found in the specification, for example at page 8, lines 27-28.

Claim 39 has been amended to correct the informality kindly pointed out by the Office.

Claim Objections

The Office has objected to claims 23, 27, 28-33, 38-40, 44-47 and 49 for the use of the term collagen-like which is alleged to render the scope of the claims unascertainable. Reconsideration of this objection is respectfully requested.

Applicant believes that the scope of the term "collagen-like" was and is clear in light of applicant's specification and is ascertainable by one skilled in the art. Applicant's specification

at page 3, lines 8-19 is noted.

In addition, applicant notes that the collagen-like peptide recited in base claim 23 is specifically defined as comprising at least one GXY domain having a length of at least 5 consecutive GXY triplets and by other features as set forth in the claim. Furthermore, the term "collagen-like" appears to be accepted in the art as illustrated by a recently conducted online keyword search of issued United States patents at http://patft.uspto.gov/netahtml/PTO/search-adv.htm. This keyword search yielded the following result:

> **Results of Search in US Patent Collection db for:**
> **SPEC/"collagen-like"**: 354 patents.
> *Hits **1** through **50** out of **354***

Cappello et al. U.S. Patent No. 5,496,712, of record herein, is also illustrative of the usage.

The typographical error in Claim 39 has been corrected as kindly suggested by the Examiner. The suggestion is appreciated by applicant.

Claim Rejections - 35 U.S.C. § 112 Second Paragraph

Claim 31 was rejected on the ground that the statement "wherein said recombinant collagen-like peptide is homodisperse" was allegedly confusing. Claim 31 has been amended to clarify that the claimed peptide is homodisperse with regard to its molecular weight. Some usages of the term "homodisperse" in applicant's specification are explained at page 4 (lines 19-30) of the specification. The term "homodisperse" is believed to be clearly understood by one skilled in the art who will, in applicant's view, have no difficulty in understanding amended claim 31. Also, applicant believes claim 31 was and is free of grammatical error.

Claim 32 has been amended to remove the objectionable language and is believed clear in its amended form.

Claim Rejections - 35 U.S.C. § 102(b)

In the outstanding Action, claims 23, 25, 30, 31, 33, 38, 40, 42 and 44-49 were rejected as allegedly being anticipated by Weber et al. U.S. Patent No. 5,801,045. Applicant believes that claims 23, 25, 30, 31, 33, 38, 40, 42 and 44-49 are in fact clearly distinguished from Weber et al. or any other art known to applicant, for reasons which are explained below.

Independent base claim 23 recites a process for preparing an oil-in-water emulsion wherein a recombinant collagen-like polypeptide is used as stabilizer of the emulsion. An oil-in-water emulsion is generally understood to be a dispersion of oil droplets in an aqueous phase. Without being bound by any particular theory, it can also be understood that the polypeptide recited in claim 23 stabilizes the hydrophobic oil droplets within the aqueous phase of the emulsion by being located at the oil-droplet-to-water interface.

Weber does not disclose a process for making an oil-in-water emulsion, and base claim 23 is accordingly distinguished from Weber et al. for this reason alone. Weber et al. discloses the use of recombinant peptides to prepare silver-halide emulsions. However, silver-halide emulsions are dispersions of solid silver-halide crystals in aqueous solutions. (See, for example Example 3 in column 20 of Weber et al.). They are not oil-in-water emulsions as is required by applicant's claims. No reference is made in Weber et al. to the use of recombinant gelatin in oil-in-water emulsions, or to oil-in-water emulsions at all. Nor has the Office asserted that Weber et al. discloses an oil-in-water emulsion.

Applicant believes that it is well recognized in the art that a dispersion of insoluble particles in a liquid phase is quite different from an emulsion employing immiscible hydrophobic and hydrophilic liquid phases. Different types of emulsions exist in the art, such as water-in-oil (W/O) and oil-in-water (O/W) emulsions, and each has different properties. Weber et al. does not describe the formation of oil droplets or their dispersion in water. Weber et al. describes the formation of solid silver halide crystals in an aqueous phase.

Furthermore, the biopolymers employed by Weber et al. are not used as stabilizers in oil-in-water emulsions, "in an amount sufficient to stabilize the emulsion" as is required by base

claim 23 (line 2). Weber et al.'s biopolymers are employed as "nucleation peptizers" in silver halide emulsions, which do not comprise oil or oil droplets. For these reasons, the process claimed in claim 23, is believed clearly distinguished from Weber et al.

Independent base claim 44 also contains limitations relating to an oil-in-water emulsion wherein a recombinant collagen-like polypeptide is used as stabilizer of the emulsion. Accordingly, claim 44 is believed clearly distinguished from Weber et al. or any other art, for the same reasons that claim 23 is distinguished.

Claims 25 and 27-40 depend from base claim 23, and accordingly contain all the limitations of claim 23. Also, claims 45-49 depend from base claim 44, and accordingly contain all the limitations of claim 44. Claims 25 and 27-40, as well as claims 45-49, are therefore believed clearly distinguished from Weber et al. for the same reasons that their respective parent base claims 23 and 44 are distinguished from Weber et al.

Dependent claims 25, 27-40, 42 and 45-49 are furthermore believed clearly and patentably distinguished from Weber et al. or any other art known to applicant by the additional meaningful limitations they recite.

For example, wth regard to claims 33 and 45, the Office has asserted that the Weber et al. patent teaches emulsions comprised of collagen-like peptides that would have an amphiphilic structure when dispersed in aqueous solution. Applicant respectfully submits that this is not accurate, as will now be explained.

Pursuant to the language of the claims, the amphiphilic peptide structure recited in applicant's claims 33 and 45 includes a polar part and an apolar part. The biopolymers of Weber et al. do not comprise a polar part and an apolar part and therefore are not amphiphilic in character, in applicant's view. Nor do Weber et al.'s biopolymers have polar and apolar parts containing at least 10 respectively polar or apolar amino acids, as is now required by applicant's claim 33. Instead, the polymers of Weber et al. are believed to be generally polar without any particular regions having a distinguishable polarity or apolarity. For example, peptide of

formulae I, as described in the abstract of Weber et al. with n=1, can be calculated to have a polarity of -2.1, using the method described on page 8 of the present application, as follows:

$$10 * 1.0 \text{ (Gly)} + 10 * -0.2 \text{ (Pro)} + 2 * -4.1 \text{ (Gln)} + 8 * -8.2 \text{ (Glu)} / 30 = -2.1$$

The resultant polarity value of -2.1 indicates the peptide is polar.

Similar calculations can be applied to the compounds of Formulae II and III of Weber et al. to show they have a negative value and are therefore also polar. No polar or apolar regions can be identified in these peptides by one skilled in the art because both polar and apolar amino acids will be understood to be randomly distributed throughout the peptide, without forming blocks of one particular polarity type, in applicant's view. For these reasons, applicant believes Weber et al. does not disclose a collagen-like peptide having an amphiphilic structure.

As can be seen from Example 5 on page 18 of applicant's specification, useful embodiments of the invention claimed in applicant's claims 33 and 45 employing amphiphilic collagen-like peptides having a distinct polar part and a distinct apolar part, each being respectively at least 10 polar or 10 apolar amino acids in length, can provide advantages, such as a reduction of droplet size in the emulsions.

In introducing the argument for the rejection of claims 33 and 45, the Office asserts that the polymers of Weber et al. are capable of forming "a micelle type emulsion in aqueous solution" and therefore "would have a polar region at one end and an non-polar region at the other end." Applicant respectfully believes this conclusion is incorrect. The ability of a substance to dissolve in an aqueous solution does not make a substance "inherently" amphiphilic. As shown above, Weber et al.'s peptides do not have distinctly polar and apolar regions. Yet, because of their overall polar nature, they would be expected to dissolve in aqueous solutions. Claims 33 and 45, as well as claims 34 and 35 which depend from claim 33 are accordingly believed furthermore clearly distinguished from Weber et al. for the additional subject matter they recite.

Claim 42 is directed to a pharmaceutical product prepared by the method of claim 25 and accordingly is also not anticipated for the same reasons that claim 25 is believed not anticipated.

Reconsideration and withdrawal of the rejection of claims 23, 25, 30, 31, 33, 38, 40, 42 and 44-49 under 35 U.S.C. § 102(b) are respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 23, 25, 27-40, 42, 44-49 were rejected as allegedly being unpatentable over Weber et al., in view of Connelly et al. (U.S. Patent No. 5,998,120) and further in view of Cappello et al. (U.S. Patent No. 5,496,712). Applicant respectfully believes that this rejection is no more applicable to the claims than were the rejections based on Weber et al. alone.

As explained above, Weber et al. does not disclose a method for making an oil-in-water emulsion which employs a collagen-like recombinant peptide to stabilize the emulsion, or products derived therefrom. Weber et al. merely discloses certain recombinant collagen-like polypeptides and their use in preparing silver-halide dispersions.

In contrast, the invention claimed in base claims 23 and 44 relates to the finding that recombinant collagen-like peptides can be used for stabilizing oil droplets in oil-in-water emulsions. Also, the stabilizing effect of the recombinant collagen-like peptides at the droplet-water interface can result in less surfactant being required at the interface. Such benefits are demonstrated in Example 4 on page 17 of applicant's specification. These surprising benefits are not remotely suggested by Weber et al., or by any other art known to applicant.

Weber et al. discloses neither oil-in-water emulsions nor amphiphilic polypeptides. As explained above, the Examiner's argument that there is an inherent disclosure of amphiphilic peptides is believed to be incorrect because Weber et al. does not disclose a molecule having polar and apolar parts. In fact, Weber et al. only describes hydrophilic, polar peptides in aqueous silver-halide dispersions.

In view of these deficiencies of Weber et al. as the primary reference, it is believed clear

that Weber et al. does not remotely suggest applicant's invention as claimed in claims 23 and 44. One skilled in the art will expect that the physico-chemical properties required to stabilize oil droplets in the aqueous phase of an oil-in-water emulsion will be quite different from those that enable a molecule to function as a silver halide nucleation or growth peptizer.

Accordingly, it is believed that applicant's base claims 23 and 44 are not obvious in view of Weber et al. as Weber et al. neither recognizes nor suggests that recombinant collagen-like peptides can be used as stabilizers of oil-in-water emulsions nor teaches how to design peptides suitable for this purpose. Furthermore, applicant's base claims 23 and 44 are believed patentably distinguished from any combination of Weber et al. with Connelly et al., were there any motivation to combine these references. Applicant does not believe there is any motivation to combine Weber et al. with Connelly et al. Nor has the Office provided any.

Connelly et al. was relied upon to show that it was well known in the art that modifying the isoelectric points of gelatin and the pH of the solution would affect its viscosity and the micelle size. The relevance of this teaching to applicant's claimed invention is respectfully not understood. Connelly et al. concerns a process for making a direct dispersion of a photographically useful material. Applicant assumes the Office uses the term "micelle" to refer to the organic phase photographic particles dispersed within an aqueous phase comprising natural gelatin that are disclosed in Connolly et al.'s claim 1, at column 15. However, the presently claimed invention is not remotely related to "micelles" of the type described in Connelly et al.. This is because in applicant's claimed emulsions the recombinant peptide acts to stabilize the oil droplets, which can be achieved by the presence of the recombinant peptides at the oil-to-water phase interface.

In contrast Connelly et al.'s natural gelatin is present within the aqueous phase of the dispersion to modify the viscosity of the solution. Connelly et al. relates only to natural gelatin, extracted from bones, and not to recombinant gelatins produced by expression of DNA sequences in microorganisms. The naturally sourced gelatin is hydrophilic and is dispersed within an aqueous solution. See claim 1, column 1, line 23 and column 2, lines 26-27 of Connelly et al. As previously stated, the dissolved natural gelatin is used to modify the viscosity

of the dispersion, and it is not used as a stabilizer of oil-droplets of an oil-in-water emulsions. Connelly et al. is therefore, believed to be not at all relevant to applicant's claimed invention. This is because the properties described in Connelly et al., such as optimization of pH and viscosity, relate to natural gelatin and to methods for making dispersions, and is unrelated to the presently claimed invention. The properties of natural gelatin do not allow the skilled person to make inferences regarding the properties of recombinant collagen-like peptide, in applicant's view. Thus Connelly et al. cannot cure the deficiencies of Weber et al. as a reference, even if a motivation to combine Connelly et al. with Weber et al. were present, which applicant does not believe is the case. Applicant's claims are accordingly believed patentable over any combination of Connelly et al. with Weber et al.

Though not stated in the Office action, Cappello et al. appears to be relied upon with respect to the subject matter of claim 34. However, it is respectfully suggested that the Office may have misunderstood claim 34. Claim 34 relates to a polar part and an apolar part, i.e. two distinct stretches of amino acids, each comprising at least 10% of the peptide backbone, as is described on page 8 of applicant's specification). Cappello et al. does not teach peptides having such amphiphilic structure or their use as stabilizers in oil-in-water emulsions. Accordingly, even were Cappello et al. to be combined with Connelly et al. and Weber et al. or with Weber et al. alone, which applicant does not believe there is any motivation to do, neither combination would remotely suggest the invention claimed in claim 34, or any other claim, in applicant's view.

In some embodiments of the invention, for example as claimed in claims 33 and 45, amphiphilic peptides, having at least one polar part and one apolar part can be used. Such embodiments can provide the advantages of reduced oil droplet size and increased age-related size stability of the droplets.

Regarding claim 35, the Examiner states that Weber et al. and the present application both comprise peptides with a polar and apolar part and that the applicant has the burden to show that the average energy transfer of the amino acids at either end would not be the same. As explained above, Weber et al.'s polypeptides do not appear to have distinct apolar parts and are overall polar. The peptides of Weber et al. are therefore not amphiphilic and one cannot calculate

energy transfer between different "distinct parts", as no polar and apolar parts are distinguishable. Accordingly, the additional subject matter of claims 35 and 45 provides additional reason for the patentability of these claims over Weber et al.

In light of the foregoing explanation, applicant respectfully requests reconsideration and withdrawal of the rejections under 35 USC § 103.

Claim Rejections – Double Patenting

A terminal disclaimer is filed herewith to overcome the double patenting rejection.

Conclusion

In view of the above amendments and the discussion relating thereto, it is respectfully submitted that the instant application, as amended, is in condition for allowance. Favorable reconsideration and allowance are earnestly solicited. If for any reason the Examiner feels that consultation with Applicant's representative would be helpful in the advancement of the prosecution, the Examiner is invited to call the undersigned practitioner below for an interview.

Respectfully submitted,

By: _____

Roger Pitt
Reg. No. 46,996
Tel. No. (212) 536-4867

KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP
599 Lexington Avenue (33rd Floor)
New York, NY 10022-6030

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope, postage prepaid, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 30, 2006.

_____

Roger Pitt, Reg. No. 46,996